



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: William F. SWAIN *et al.*

Title: DNA-VACCINES BASED ON CONSTRUCTS
DERIVED FROM THE GENOMES OF
HUMAN AND ANIMAL PATHOGENS

Appl. No.: 09/705,149

Filing Date: 11/1/2000

Examiner: Bao Q. Li

Art Unit: 1648

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This communication is responsive to the Restriction Requirement set forth in the Office Action, dated May 5, 2004, concerning the above-referenced patent application. The period for response has been extended up to July 6, 2004 (July 5, 2004 being a holiday) by the one (1) month extension of time included in the attached Transmittal. Although applicants believe that the amount of the attached check is correct, the Commissioner is hereby authorized to credit any overpayment or to charge any deficiency to Deposit Account No. 19-0741.

In response to the restriction requirement, Applicants provisionally elect Group III, Claims 15-25, for examination, with traverse. Applicants expressly reserve their right under 35 U.S.C. § 121 to file one or more divisional applications directed to the non-elected subject matter during the pendency of this application.

The Examiner has required restriction between Claims 1-8 (Group I), drawn to a method for eliciting an immune response by administering a plasmid construct comprising a

genomic fragment between 5-25 kilobases in size; Claims 1 and 9-14 (Group II), drawn to a method for eliciting an immune response by administering a cosmid construct comprising a genomic fragment between 25-50 kilobases in size; Claims 15-25 (Group III), drawn to a method for eliciting an immune response by administering a plasmid construct coated with gold as a core carrier, wherein the antigen comprises a genomic fragment between 5-50 kilobases in size; Claims 15 and 26-34 (Group IV), drawn to a method for eliciting an immune response by administering a cosmid construct coated with gold as a core carrier, wherein the antigen comprises a genomic fragment between 25 kilobases and 50 kilobases in size; Claims 35-37 (Group V), drawn to a method for identifying a sequence; Claims 38-48 and 51 (Group VI), drawn to a vaccine composition comprising a plasmid construct having a genomic fragment between 5-25 kilobases in size as antigen; and Claims 38-45 and 49-51 (Group VII), drawn to a vaccine composition comprising a cosmid construct having a genomic fragment between 25-50 kilobases in size as antigen.

Election of Group III is made with traverse for the following reasons. First, applicants wish to point out that, in a previous restriction requirement in the same application, dated July 5, 2001, the Examiner restricted applicants' claimed invention between the same seven groups identified above. Moreover, the Examiner matched these groups with essentially the same claims.¹ In their January 3, 2002 response, applicants provisionally elected Group III, with traverse, and provided reasons why Groups III and IV should be reconsidered and recombined. In the following Office Action, dated April 5, 2002, the Examiner kindly agreed to examine Groups III and IV together, indicating that all of the claims use the same method to deliver cosmids.

On December 3, 2002, the Examiner closed prosecution by mailing a final Office Action. On December 2, 2003, applicants filed a response to the final Office Action and a Request for Continued Examination ("RCE") under 37 C.F.R. § 1.114. Section 1.114 states that "[i]f an applicant files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will be entered and considered."

¹ The exception is that Group V now excludes claim 38 and Group VI now includes claim 51.

Applicants submit that, by filing an RCE, they requested that the PTO continue examination of the pending, elected claims and that, in accordance with section 1.114, the PTO withdraw the finality of the December 3, 2002 Office Action and consider applicants' submission on the merits. *See* MPEP § 706.07(h). By improperly issuing the restriction requirement of May 5, 2004 in this matter, the Examiner failed to consider and respond to applicants' submission.

Moreover, the MPEP advises examiners to issue restriction requirements early in the process. The Examiner provides no reason for issuing such a late restriction requirement, especially since the Examiner has already issued an essentially identical restriction requirement in this matter. *See* MPEP § 811. Nothing has changed in the interim and applicants clearly indicated in their last response that claims 1-14 and 35-51 were withdrawn from further consideration. Accordingly, applicants respectfully request that the Examiner continue to examine the claims that are presented for prosecution, claims 15-34.

Further, for the reasons already of record and because the claims use the same method to deliver cosmid, applicants respectfully submit that Groups III and IV should be rejoined. Applicants note that the Office has characterized all of the claims of Group III to be limited to plasmids "coated with gold as a core carrier." This is incorrect. For example, claim 15 clearly encompasses genetic constructs coated onto any core carrier (not genetic constructs coated with gold, or even just gold carrier particles). In addition, the Office has asserted that all claims are limited to plasmid constructs containing a genomic fragment from 5-25 kilobases in size. However, applicants note that claim 15 recites constructs of 5 kilobases or larger. Reconsideration and clarification of the Group III claim scope is thus respectfully requested.

With respect to Group IV, applicants assume that the Office has intended to group all cosmid constructs together. However, in the description of the Group IV claims, the Office has referred to plasmid constructs only. Applicants believe that the proper grouping for Group IV would be claims 15, 16, and 22-34, and further that the constructs should be cosmids, not plasmids. Reconsideration is thus respectfully requested.

Accordingly, for all of the foregoing reasons, reconsideration and modification of the restriction requirement is respectfully requested.

Respectfully submitted,

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